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| Substitute Form PTO-1449<br>(Modified)<br><br><b>Information Disclosure Statement<br/>by Applicant</b><br>(Use several sheets if necessary)<br><br>(37 CFR §1.98(b)) | U.S. Department of Commerce<br>Patent and Trademark Office | Attorney's Docket No.<br>06275-150003 | Application No.<br>10/010,283 |
|  | Applicant<br>Carl-Axel Bauer <i>et al.</i>                 |                                       |                               |
|  | Filing Date<br>November 13, 2001                           | Group Art Unit<br>1617                |                               |

**U.S. Patent Documents**

| Examiner Initial | Desig. ID | Document Number | Publication Date | Patentee | Class | Subclass | Filing Date If Appropriate |
|------------------|-----------|-----------------|------------------|----------|-------|----------|----------------------------|
|                  | BA        |                 |                  |          |       |          |                            |

**Foreign Patent Documents or Published Foreign Patent Applications**

| Examiner Initial | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation |    |
|------------------|-----------|-----------------|------------------|--------------------------|-------|----------|-------------|----|
|                  |           |                 |                  |                          |       |          | Yes         | No |
|                  | BB        | WO 97/11783     | 04/03/1997       | WIPO                     |       |          |             |    |

**Other Documents (include Author, Title, Date, and Place of Publication)**

| Examiner Initial | Desig. ID | Document  |
|------------------|-----------|---|
|                  | BC        | "American Thoracic Society: Standards for the Diagnosis and Care of Patients with Chronic Obstructive Pulmonary Disease," <i>Am. J. Respir. Care Med.</i> 152:S77-S121 (1995)   |
|                  | BD        | "Atemstillstand" <i>Pschyrembel Klinisches Wörterbuch</i> (2002) (in German)  |
|                  | BE        | Auffarth <i>et al.</i> , "Effects of inhaled budesonide on spirometric values, reversibility, airway responsiveness, and cough threshold in smokers with chronic obstructive lung disease" <i>Thorax</i> 46:372-377 (1991)                    |
|                  | BF        | Barnes, "Inhaled steroids in COPD" <i>The Lancet</i> 351:766-767 (1998)   |
|                  | BG        | Basic Reference Manual, vol. 1, revised ed. of 1988, issued by IMS International  |
|                  | BH        | "Bronchodilators and anti-inflammatories," <i>Monthly Index of Medical Specialities (MIMS)</i> 242-256 (09/1997)  |
|                  | BI        | Boyd <i>et al.</i> , "An Evaluation of Salmeterol in the Treatment of Chronic Obstructive Pulmonary Disease (COPD)," <i>Eur. Resp. J.</i> 10:815-821 (1997)   |
|                  | BJ        | Burge <i>et al.</i> , "Randomised, double blind, placebo controlled study of fluticasone propionate in patients with moderate to severe chronic obstructive pulmonary disease: the ISOLDE trial," <i>British Med. J.</i> 320:1297-1303 (2000) |
|                  | BK        | Davies <i>et al.</i> , "Oral corticosteroid trials in the management of stable chronic obstructive pulmonary disease," <i>Q. J. Med.</i> 92:395-400 (1999)  |
|                  | BL        | "Disorders of the Airways," <i>Current Medical Diagnosis and Treatment</i> 1997 36 <sup>th</sup> ed. pages 241-255, Stamford, CT: Appleton and Lange (1997)   |
|                  | BM        | Dompeling <i>et al.</i> , "Slowing the deterioration of Asthma and Chronic Obstructive Pulmonary Disease Observed during Bronchodilator Therapy by Adding Inhaled Corticosteroids," <i>Ann. Intern. Med.</i> 118(10):770-778 (1993)           |
|                  | BN        | Engel <i>et al.</i> , "A trial of inhaled budesonide on airway responsiveness in smokers with chronic bronchitis" <i>Eur. Respir. J.</i> 2:935-939 (1989)   |
|                  | BO        | Fabbri <i>et al.</i> , "Global Strategy for the Diagnosis, Management and Prevention of COPD: 2003 update" <i>Eur. Respir. J.</i> 22:1-2 (2003)   |
|                  | BP        | Flenley, "Chronic Obstructive Pulmonary Disease," <i>Disease-A-Month</i> 34:549-599 (1988)  |
|                  | BQ        | "Foradil" <i>Compendium Suisse des Medicaments</i> , Supplement 1a pages 7-8 (1991) (in French)   |

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| Substitute Form PTO-1449 (Modified)<br>NOV 04 2003<br>U.S. Department of Commerce<br>Patent and Trademark Office<br><b>Information Disclosure Statement</b><br>by Applicant<br>(Use several sheets if necessary)<br>(37 CFR §1.98(b)) | Attorney's Docket No.<br>06275-150003      | Application No.<br>10/010,283 |
|   | Applicant<br>Carl-Axel Bauer <i>et al.</i> |                               |
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|                  | BR        | "Foradil." <i>Compendium Suisse des Medicaments</i> , 15th Ed. 1997/1998, Ed. Grand Public, compiled June 1996, pages 419-420, 866 (in French)  |
|                  | BS        | "Foradil." <i>Compendium Suisse des Medicaments</i> , 18th Ed. 1997, compiled June 1996, pages 849-850 and 1635 (in French)   |
|                  | BT        | "Foradil" Patient information leaflet, published by IKS, Switzerland (12/1990) (in French)  |
|                  | BU        | Gibson <i>et al.</i> , <i>Respiratory Medicine</i> Table of contents (2002)   |
|                  | BV        | "GOLD: Global Initiative for Chronic Obstructive Lung Disease," Executive Summary; National Institutes of Health, National Heart Lung and Blood Institute, NIH Publication No. 2701A, pages 1-30 (03/2001)                                |
|                  | BW        | "GOLD: Global Initiative for Chronic Obstructive Lung Disease; Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease," based on April 1998 NHLBI/WHO Workshop, pages 1-100 (2004 Update) |
|                  | BX        | Jeffery "Structural and inflammatory changes in COPD: a comparison with asthma" <i>Thorax</i> 53:129-136 (1998)   |
|                  | BY        | Keatings <i>et al.</i> , "Effects of Inhaled and Oral Glucocorticoids on Inflammatory Indices in Asthma and COPD" <i>Am. J. Respir. Crit. Care Med.</i> 155:542-548 (1997)  |
|                  | BZ        | Kerstjens <i>et al.</i> , "A Comparison of Bronchodilator Therapy with or without Inhaled Corticosteroid Therapy for Obstructive Airways Disease," <i>New Eng. J. Med.</i> 327:1413-1419 (1992)   |
|                  | BAA       | Leff <i>et al.</i> , "Therapeutic Regimens in Chronic Obstructive Pulmonary Disease," <i>Pulmon. Crit. Care Pharmacol. Therapeut. Ch.</i> 86:837-844 (1996)   |
|                  | BBB       | Niewoehner <i>et al.</i> , "Effect of Systemic Glucocorticoids on Exacerbations of Chronic Obstructive Pulmonary Disease" <i>New Eng. J. Med.</i> 340(25):1941-1947 (1999)  |
|                  | BCC       | Norman, "COPD: New Developments and Therapeutic Opportunities" <i>Drug News Perspect.</i> 11(7):431-437 (1998)  |
|                  | BDD       | Pauwels <i>et al.</i> , "Long-Term Treatment with Inhaled Budesonide in Persons with Mild Chronic Obstructive Pulmonary Disease Who Continue Smoking" <i>N. Eng. J. Med.</i> 340:1948-1953 (1999)   |
|                  | BEE       | Postma, "Inhaled therapy in COPD: what are the benefits?" <i>Respiratory Medicine</i> 85:447-449 (1991)   |
|                  | BFF       | "Pulmicort" ABPI Data Sheet Compendium, p. 146-147 (1995/1996)  |
|                  | BGG       | Schultze-Werninghaus, "Multicenter 1-Year Trial on Formoterol, a New Long-Acting $\beta_2$ -Agonist, in Chronic Obstructive Airway Disease," <i>Lung Suppl.</i> 83-89 (1990)  |
|                  | BHH       | Siafakas <i>et al.</i> , "Optimal Assessment and Management of Chronic Obstructive Pulmonary Disease (COPD)," <i>Eur. Respir. J.</i> 8:1398-1420 (1995)   |
|                  | BII       | Soriano <i>et al.</i> , "Inhaled Corticosteroids with/Without Long-Acting b-Agonists Reduce the Risk of Rehospitalization and Death in COPD Patients," <i>Am. J. Respir. Med.</i> 2:67-74 (2003)  |
|                  | BJJ       | Stalenheim <i>et al.</i> , "Efficacy and Tolerance of a 12-Week Treatment with Inhaled Formoterol in Patients with Reversible Obstructive Lung Disease," <i>Respiration</i> 61:305-309 (1994)   |
|                  | BKK       | Stedman's Medical Dictionary, 25 <sup>th</sup> ed., Baltimore: Williams and Wilkins; page 428   |
|                  | BLL       | Szafranski <i>et al.</i> , "Efficacy and safety of budesonide/formoterol in the management of chronic obstructive pulmonary disease" <i>Eur. Respir. J.</i> 21:74-81 (2003)   |

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|------------------|-----------|---|
|                  | BMM       | Trechsel, "Foradil in medical practice; 7 case studies" Ciba Geigy (1992)   |
|                  | BNN       | Van Schayck <i>et al.</i> , "Do patients with COPD benefit from treatment with inhaled corticosteroids?" <i>Eur. Respir. J.</i> 9:1969-1972 (1996)  |
|                  | BOO       | Vestbo <i>et al.</i> , "Long-term effect of inhaled budesonide in mild and moderate chronic obstructive pulmonary disease: a randomised controlled trial," <i>Lancet</i> 353:1819-1823 (1999)                     |
|                  | BPP       | Watson <i>et al.</i> , "Failure of Inhaled Corticosteroids to Modify Bronchoconstrictor or Bronchodilator Responsiveness in Middle-Aged Smokers with Mild Airflow Obstruction" <i>Chest</i> 101(2):350-355 (1992) |
|                  | BQQ       | Weiner <i>et al.</i> , "Inhaled Budesonide Therapy for Patients with Stable COPD," <i>Chest</i> 108:1568-1571 (1995)  |

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